REMARKS/ARGUMENTS

The Office Action mailed April 12, 2007, has been received and reviewed. Claims 1 through 35 are currently pending in the application. Claims 15 and 29 have been withdrawn from consideration as being drawn to non-elected invention(s). Claims 1 through 14, 16 through 28, and 30 through 35 stand rejected. Applicants have amended claims 1 and 5, and respectfully request reconsideration of the application as amended herein.

Priority

The Examiner objected to paragraph **[0001]** of the specification as designating application 09/585,590 as a "utility conversion" of a provisional application. Paragraph **[0001]** of the specification has been amended above in compliance with the Examiner's request for correction.

Specification

The Examiner objected to the disclosure as referring to application serial number 08/993,208, which has now issued as a U.S. patent. The specification has been amended above to update the status of this application in compliance with the Examiner's request.

Drawings

The Examiner objected to FIG. 1 of the drawings as "informal." Applicants filed formal Replacement Sheets with the U.S. Patent and Trademark Office on September 12, 2005, but because it appears that the Examiner did not receive the September 12, 2005 Replacement Sheets, Applicants have included a second set of formal Replacement Sheets with this Amendment.

Claim Objections

The Examiner objected to Claim 9 because of a writing informality. Claim 9 has been corrected in the Amendment set forth above.

35 U.S.C. § 102(b) Anticipation Rejections

Anticipation Rejection Based on U.S. Patent No. 5,662,933 to Baichwal et al., in Light of Information from rxlist.com

Claims 1, 2, 8, and 10 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Baichwal et al. (U.S. Patent No. 5,662,933), taken in light of information from rxlist.com (Combivent reference). Applicants respectfully traverse this rejection, as hereinafter set forth.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Brothers v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

The 35 U.S.C. § 102(b) anticipation rejections of claims 1, 2, 8, and 10 are improper because the cited reference does not disclose each and every element of the claims.

Claim 1 has been amended to recite a composition comprising a carrier and particulates comprising a compressed mixture of an active agent and an agent exhibiting a characteristic of low solubility in water, wherein the hydrophobic agent is selected from the group consisting of pharmaceutically acceptable oil, fats, fatty acids, fatty acid esters, waxes and mixtures an derivatives thereof that exhibit the hydrophobic characteristic, the particulates being dispersed within the carrier. As acknowledged by the Examiner, Baichwal et al. does not disclose a composition having a hydrophobic agent selected from the group consisting of pharmaceutically acceptable oil, fats, fatty acids, fatty acid esters, waxes and mixtures an derivatives thereof that exhibit the hydrophobic characteristic (previously recited in dependent claim 3). Additionally, Baichwal et al. does not disclose a compressed mixture of an active agent and an agent exhibiting a characteristic of low solubility in water. As such, Applicants respectfully request withdrawal of the present rejection.

35 U.S.C. § 103(a) Obviousness Rejections

Obviousness Rejection Based on U.S. Patent No. 6,130,200 to Brodbeck et al., in View of U.S. Patent No. 5,628,993 to Yamagata et al. and U.S. Patent No. 6,096,339 to Ayer et al.

Claims 1 through 14, 16 through 28, and 30 through 35 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Brodbeck et al. (U.S. Patent No. 6,130,200), taken in view of Yamagata et al. (U.S. Patent No. 5,628,993) and Ayer et al. (U.S. Patent No. 6,096,339). Applicants respectfully traverse this rejection, as hereinafter set forth.

M.P.E.P. 706.02(j) sets forth the standard for a Section 103(a) rejection:

> To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, **the prior art reference (or references when combined) must teach or suggest all the claim limitations.** The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). (Emphasis added).

The 35 U.S.C. § 103(a) obviousness rejections of claims 1-14, 16-28, and 30-35 are improper because the cited references do not teach all of the claim limitations.

Brodbeck is relied upon as teaching a sustained-release pharmaceutical composition comprising particles of spray-dried, lyophilized human growth hormone and zinc acetate suspended in a gel of poly-(D,L-lactide-co-glycolide) (PLGA, a biocompatible gel carrier) and benzyl benzoate. (Office Action at pg. 5).

Brodbeck, as described in the Description of Related Art section of the application (page 4, lines 10-21), is drawn to a system based on polymer/solvent compositions that form a gel and control the rate of ingress of water into the bulk polymeric system. The Examiner appears to argue that Brodbeck discloses the compressed particles of the present invention because the lyophilized drug particles disclosed therein are "compressed" in the same sense as the particulates used in the present invention, due to their size (2-100 micron particles). Thus, the Examiner is interpreting the term "compressed" in the present claims as meaning merely "small". Applicants respectfully submit that this interpretation is incorrect.

The particulates used in the present invention are "compressed" in the sense that they have been subjected to compression, i.e. put under high pressure, for example by tableting, roller compaction, or extrusion (see, for example, paras. [0038] and [0039]). Compression is accomplished at "pressures high enough to compact the material and produced a compacted body". The compacted body is then "milled or ground to form particulates..." (Id.). Compression reduces the ratio of surface area to mass of the particulates, i.e. increases their density, which reduces the burst of beneficial agent from implantable systems, and clearly does not determine their particle size, contrary to the assertions of the Examiner. The particle size of the particulates is instead determined by the milling or grinding to which the compressed material is subsequently subjected, which step is unconnected to the compression step. Accordingly, the term "compressed" as used in the present claims clearly refers to particulates which have been formed from material which has been subjected to pressure, and is not merely used as an equivalent term to "small".

As discussed in the present application, compression reduces the ratio of surface area to mass of the particulates, and reduces the rate of dissolution, dispersion or diffusion of the beneficial agent when exposed to bodily fluids in an environment of use. The composition of the present invention can thus reduce the burst of beneficial agent, and increase the loading capacity of the carrier, so that delivery of the beneficial agent may be extended over a prolonged period of time. This allows for fewer doses where administration of beneficial agent must be carried out over a prolonged period of time. The technical problem of how to increase the loading capacity of the carrier whilst reducing burst of beneficial agent is simply not addressed by the cited prior art documents. A skilled person reading the cited prior art documents would not be obviously lead to the present invention, and we submit that the present invention is thus patentable over the disclosure of these documents.

Thus, Brodbeck does not disclose, teach or suggest a composition which comprises particulates which have been compressed, as described above. Indeed, there is no mention or suggestion whatsoever in Brodbeck to the use of compressed particulates, per the present invention.

As acknowledged by the Examiner, Brodbeck does not teach or suggest hydrophobic agent is selected from the group consisting of pharmaceutically acceptable oil, fats, fatty acids, fatty acid esters, waxes and mixtures an derivatives thereof that exhibit the hydrophobic characteristic. To overcome this particular deficiency, the Examiner relies on Yamagata as teaching a composition comprising powdered particles of interferon-α dispersed in a matrix of tetraglycerol dipalmitate or tetraglycerol. Ayer is also relied upon as teaching particles comprising active agents that are included in compositions that may be made by spray-drying or crushing. (Office action at pg. 6). However, Yamagata and Ayer do not overcome the deficiencies of Brodbeck. Specifically, Yamagata and Ayer do not teach or suggest a compressed mixture of an active agent and an agent exhibiting a characteristic of low solubility in water.

In view of the foregoing amendments and arguments, Applicants respectfully request withdrawal of the present rejection to claims 1-14, 16-28, and 30-35.

ENTRY OF AMENDMENTS

The amendments to claims 1 and 5 above should be entered by the Examiner because the amendments are supported by the as-filed specification and drawings and do not add any new matter to the application.

CONCLUSION

Claims 1-14, 16-28, and 30-35 are believed to be in condition for allowance, and an early notice thereof is respectfully solicited. Should the Examiner determine that additional issues

remain which might be resolved by a telephone conference, he is respectfully invited to contact Applicants' undersigned attorney.

Respectfully submitted,

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Attachments: Replacement Sheets (formal drawings)